

**OPTN Ad Hoc Disease Transmission Advisory Committee
Review of Policy Rewrite Public Comment**

August 2, 2012 Teleconference

Committee Members Present:

Michael Green, MD, MPH (Chair)
Daniel Kaul, MD (Vice-Chair)
Donna Ennis, RN, BS, CCTC
Thomas Gross, MD, PhD
Mary Klassen-Fischer, MD
Marilyn Menegus, PhD
Rachel Miller, MD
Timothy Pruett, MD
Dianne LaPointe-Rudow ANP, DrNP, CCTC
Phillip Ruiz, Jr, MD, PhD
Michael Souter, MD
Linda Weiss, MS, MT(ASCP)SM, CTBS
Bernard Kozlovsky, MD, MS (Ex Officio)
Karen Near, MD (Ex Officio)
Melissa Greenwald, MD (Invited Guest)
Shandie Covington (UNOS Staff)
Leigh Kades (UNOS Staff)
Shyni Mohan (UNOS Staff)

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) convened by teleconference on August 2, 2012 to review and comment upon a complete rewrite of OPTN policy. The DTAC focused its review on the rewrite of current policies 2.0 and 4.0, commenting on new policy sections 2 and 15. While a formal vote was not requested, the Committee was supportive of the effort.

During Policy Oversight Committee review of the proposed rewrite, the DTAC representative raised concerns regarding language referring to the US Public Health Service Guidelines on recognizing potential organ donors (both living and deceased) at increased risk for transmitting HIV, Hepatitis B and Hepatitis C. Because revisions currently underway by the CDC were hotly contested in the transplant community, there was concern that referencing them in OPTN policy once approved could be detrimental to organ transplantation due to the increased number of donors that would be categorized as “high risk” for potential transmission if proposed revisions were implemented. Since that time, the CDC has worked with the transplant community and revised its proposal. The updated proposed guidelines are now felt to be more acceptable to the transplant community, and the concern regarding referencing the new guidelines (anticipated for implementation in early 2013) has been alleviated. A member noted that per the Final Rule § 121.4(2), OPTN policies must be consistent with recommendations of the CDC for testing organ donors and follow up of recipients to prevent the spread of infectious diseases. Based upon this discussion, the Committee sees no need to modify references to the guidelines in the proposed OPTN policy rewrite.

During the call the following comments were shared and discussed regarding specific areas within the proposed language:

Proposed Policy 2

Proposed Policy	DTAC Comments
Policy 2 Title	Modify to “Deceased Donor Organ Procurement” since there will be a separate policy section dedicated to living donor screening and procurement. Live donor evaluation is captured in Policy 13.
2.2, sentence above second numbered list	Current policy 2.2.2.1 notes that “OPO must attempt to obtain...” The new language notes that “medical and behavioral history on each potential donor should include <i>all</i> of the following...” DTAC is concerned that intent has changed here. There are instances where consent to donate is present (signed donor card, drivers license, etc), but there may be no credible historian to provide “all” of this information, which could be construed as a policy violation.
2.2, #4 in second numbered list	This language is identical to what is in current policy except for the addition of the word “any.” The Committee is concerned regarding a requirement to identify <u>any</u> factor that could be associated with increased risk could be difficult for any OPO to attain and potentially lead to litigation in cases of disease transmission.
2.2, #5 in second numbered list	#4 and #5 should be combined, as is reflected in current policy language. The Committee believes that separating them out suggests that there are two separate set of criteria for assessing risk for blood borne pathogens. This section should outline ascertaining factors associated for increased risk of transmitting HIV, HBV and HCV as outlined in the US PHS Guidelines. (<i>*It should be noted that the 1994 (current) guidelines only define “high risk” as related to HIV transmission.</i>)
2.4(B), first line and table 2-1	Committee questions whether the first line “The Host OPO is responsible for evaluating donors according this section...” could be confusing when then looking at the table. For example, all donors are to be screened for a history of drug use. If you were only placing kidneys from a donor, would this not be required since it is not indicated as necessary for kidneys or pancreas. While the table is visually pleasing, and the committee recognizes that the requirements were pulled from organ specific language, it preferred the specific screening/testing requirements for every deceased donor being laid out in list format. The Committee is supportive of the eventual development of a universal donor screening form. This has already been done for collecting medical-social history.
2.4, third paragraph	The DTAC will be addressing the “commercially available” definition as a goal for this year. This might benefit from being marked as a parking lot issue to draw attention.
Table 2-1	Is language cut off from “Medication...” row on bottom of page 26?
2.4(D)	Would inclusion of examples (i.e. autopsy results) of what would be beneficial in #1 of second list of times for clarity? Autopsy results are sometimes overlooked.
2.4(D), last sentence	Clarifying this language may be a parking lot issue. This has been problematic as some OPOs read it to mean reporting EVERY positive culture, which is unnecessary. The guidance document helps here, but looking at it as written without consulting guidance or evaluation plan could be problematic. The DTAC is aware and considering options.

2.5, #3 in first list of numbered items	The language here is incredibly awkward per DTAC. Perhaps a clearer read would be: Any blood products administered have been screened as negative for HIV.
2.5(B)	NOTA reference was removed. Staff pointed out that the reference was present in the notes section at the end of the policy section, but members believed it was important to clearly state that this is currently prohibited by Federal law.

Proposed Policy 15

Proposed Policy	DTAC Comments
15.4(A), #5	Perhaps restate as “relevant to acute recipient care” which is language used in the guidance document?
15.5(A)	In response to parking lot comment, the Committee believes priority should be placed on OPO notification and then OPO’s notification of all other recipients. To date, both of these points have been covered in the 24 hour period outlined in policy.
15.5(B) 7	Committee would like to point out (perhaps in guidance document) that the reporting time of 2 years required for living donors is a minimum requirement, but that reporting is encouraged if new information on a donor is learned beyond that cut off point. A member suggested developing guidance based upon what has been reported in the living donor experience so far, and time span from transmission to recognition of disease or illness.